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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,244	09/29/2005	Dipti Sareen	UCSD1420-1	8727
28213	7590	01/15/2008		
DLA PIPER US LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			EXAMINER ZARA, JANE J	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 01/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,244

Applicant(s)

SAREEN ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 10-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2-27-06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>SEQ Alignment Data</u> . |

DETAILED ACTION

This Office action is in response to the communication filed 11-15-07.

Claims 1-127 are pending in the instant application.

Election/Restrictions

Applicant's election of Group I, claims 1-3 and 6-9, drawn to 1 D-myo-inosityl 2-amino-2-deoxy- α -D-glucopyranoside as the glycosaminyl inositol and a small molecule as the candidate compound type, in the reply filed on 11-15-07 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 101 & 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are drawn to methods of identifying inhibitors of cysteine:glucosaminyl inositol ligase comprising contacting a candidate compound comprising a small molecule in the presence of any polypeptide sharing at least 35% sequence identity with SEQ ID NO: 2 or 4, or conservative variations thereof.

Following the requirements of the Utility Guidelines (See Federal Register, Dec. 21, 1999, Vol. 64, No. 244, *revised guidelines for Utility*), the first inquiry is whether a credible utility is cited in the specification for use of the polynucleotides. The cited utilities in the specification are that the purportedly "novel" nucleic acids claimed, comprising any homologs sharing at least 35% sequence identity with SEQ ID NOs. 2 or 4, are sequences that are purported to have cysteine:glucosaminyl inositol ligase activity. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. Since the polynucleotides claimed are sequences derived from a conceptual model of what should encompass homologs of cysteine:glucosaminyl inositol ligase, and for the most part have not been identified in any biological systems, the credible utility appears to be lacking.

The next issue is whether there are any well established or substantial utilities for the claimed polynucleotides. No well established utilities for the breadth of claimed polynucleotides are identified in either the specification or in the prior art. The research contemplated by Applicant to characterize potential or purportedly naturally occurring polynucleotides that might act as cysteine:glucosaminyl inositol ligasees, does not constitute a specific and substantial utility. Identifying a possible polynucleotide sequence using computations or computer modeling does not define a "real world" context or use. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds such that another non-asserted utility would be well established for these purported polynucleotides (see

accompanying sequence alignment data between Acc. No. AAG91416 and the instantly claimed SEQ ID NO. 2; and between SEQ ID NO. 288 of Pompejus et al (US20070161091) and the instantly claimed SEQ ID NO. 2). There is no showing in the specification or the art that the expansive genus of polynucleotides encompassed by homologs sharing at least 35% identity with SEQ ID NOs. 2 or 4 exist in any biological context.

Claims 1-3 and 6-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial or asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to what the term "derivative thereof" in line 4 of claim 1 is referring (e.g. Is it a derivative of the cysteine or the glucosaminyl inositol, or both?). Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of identifying inhibitors of cysteine:glucosaminyl inositol ligase comprising contacting a candidate compound comprising a small molecule in the presence of any polypeptide sharing at least 35% sequence identity with SEQ ID NO: 2 or 4, or conservative variations thereof.

The specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of the genus comprising any polypeptide sharing at least 35% sequence identity with SEQ ID NO: 2 or 4, or conservative variations thereof, which provide for the function claimed, of having cysteine:glucosaminyl inositol ligase activity.

The prior art teaches numerous polypeptides sharing at least 35% sequence identity with SEQ ID NO. 2 or 4, but they are not cysteine:glucosaminyl inositol ligases (see e.g. accompanying sequence alignment data between Acc. No. AAG91416 and the

instantly claimed SEQ ID NO. 2; and between SEQ ID NO. 288 of Pompejus et al (US20070161091) and the instantly claimed SEQ ID NO. 2).

The specification teaches SEQ ID NOs. 2, 4, which purportedly provide for cysteine:glucosaminyl inositol ligase activity. The genus of homologs claimed, however, encompasses a vast array of structures. The specification, claims and art do not adequately teach a representative number of species for the broad genus claimed.

Concise structural features that could distinguish structures within the genus from others are missing from the disclosure, whereby a representative number of species is particularly described which provides for the function claimed, of providing cysteine:glucosaminyl inositol ligase activity in a representative number of species in the broad genus any nucleic acid encoding any polypeptide sharing at least 35% sequence identity with SEQ ID NO. 2 or 4, or any conservative variations thereof. For these reasons, the instant disclosure fails to provide adequate written description for the broad genus of nucleic acids claimed.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-10-08

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JANE ZARA, PH.D.
PRIMARY EXAMINER